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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,758	10/23/2000	Shukti Chakravarti	CWV-001.01	7408

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EXAMINER	
PONNALURI, PADMASHRI	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/694,758	CHAKRAVARTI, SHUKTI	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/29/05 has been entered.

2. Claims 1-29 have been canceled and new claims 30-41 have been added by the amendment filed on 3/29/05.

3. Claims 30-41 are currently pending and are being examined in this application.

4. This application claims priority to provisional application 60/160,835, filed on 10/23/00.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 30-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The instant claims recite a method for determining an IBD or pre-IBD phenotype of a test cell from a given tissue, comprising: a) contacting the mRNA of said test cell with at least 5 different nucleic acid probes, wherein each of said probes is at least 12 nucleotides in length and

is complementary to the mRNA of a gene shown in Table 1; and b) determining an approximate amount of hybridization between each of said probes and mRNA of said gene shown in Table 1, wherein said amount of hybridization either more or less to a control cell of the given tissue type indicates that said test cell has an IBD or pre-IBD phenotype.

The limitation 'at least 5 different nucleic acid probes .....is complementary to the mRNA of a gene shown in Table 1'; and 'determining an approximate amount of hybridization between each of said probes and mRNA of said gene shown in Table 1..' claimed in Claims 30-41 has no clear support in the specification and the claims as originally filed. The specification in page 42 discloses '....contacting mRNA of test cell with nucleic acid probe of at least 12 nucleotides in length, and upto all or nearly all of sequence which is complementary to a portion of the coding sequence of a nucleic acid sequence represented in Table 1.' The subject matter claimed in the new claims (i.e. determining an approximate hybridization **between of each of said probes and the mRNA of said gene shown in Table 1'**, and '5 different probes which are complementary to the mRNA of a gene shown in Table 1') has no support in the specification as originally filed.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

7. Claims 30-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claims recite a method for determining an IBD or pre-IBD phenotype of a test

cell from a given tissue, comprising: a) contacting the mRNA of said test cell with at least 5 different nucleic acid probes, wherein each of said probes is at least 12 nucleotides in length and is complementary to the mRNA of a gene shown in Table 1; and b) determining an approximate amount of hybridization between each of said probes and mRNA of said gene shown in Table 1, wherein said amount of hybridization either more or less to a control cell of the given tissue type indicates that said test cell has an IBD or pre-IBD phenotype.

The specification description is directed to a method comprising, i) generating a first library of nucleic acid probes representative of genes expressed by intestinal tissue of an animal without apparent risks or symptoms of IBD; ii) generating a second library of nucleic acid probes representative of genes expressed by intestinal tissue of animal which has symptoms of IBD; iii) identifying the genes up or down regulated, and use thus identified genes in the method of determining a phenotype of a cell. Thus genes involved in up or down regulated in **IBD condition have to be identified and probes of these genes are generated and formed micro arrays of the generated probes and the arrays in identifying phenotype of a cell as claimed.**

The specification disclosure does not recite or has given examples of the identified up or down regulated IBD genes or the probes generated from the genes identified or the micro arrays. The specification discloses that the libraries of nucleic acid probes (at least 5 genes refers to a library) for indexing the level of expression of one or more IBD genes. And the IBD probes will be isolated nucleic acids comprising a nucleotide sequence which hybridizes under stringent conditions to a sequence of table 1(e.g., see page 3). Further the specification discloses that the nucleic acid probes for indexing the level of expression of IBD genes are nucleic acid sequences (12-40 consecutive nucleic acids) correspond to the IBD gene set. The specification discloses

that 'the mRNA of a test cell is contacted with a nucleic acid probe which is at least 12 nucleotides in length...., and upto all or nearly all of a sequence which is complementary to a portion of coding sequence of a nucleic acid sequence represented in Table 1.' Thus, the IBD gene set in Table 1 is not directly used in the claimed invention. Nucleic acid sequences identical or nucleic acid sequence which is complementary to the coding sequence, and the sequence which correspond to the nucleic acid sequences of the IBD gene set in Table 1 has to be determined such that the identified nucleic acid sequences can be used as probes in the claimed method.

The claimed method depends upon identifying nucleic acid sequence probes after hybridizing with known IBD gene set, and prepare micro arrays using the identified probes and use the array in the claimed method. The specification does not disclose the nucleic acid sequences, which are identified after hybridizing with the known IBD gene set. Without knowing the probes (or nucleic acid sequences) it is impossible to practice the claimed method. Without the disclosure of the probes (or nucleic acid sequences) used in the claimed method, the specification description is hypothetical.

The specification disclosure is narrative and based on hypothetical method. The specification does not include any working examples or experiments in which the genes involved in up- or down-regulated in intestinal tissue of patients are used in the method of determining phenotype or to assess a patient's risk of having or developing an inflammatory bowel disease. Thus, applicants are not in possession of the genes involved in the IBD.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "*written description of an invention*

involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1405 (1997), quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in University of California v. Eli Lilly defined the invention by function of the claimed DNA (encoding insulin)].

Thus, it requires a representative sample of compounds and/or a showing of sufficient identifying characteristics; to demonstrate possession of the claimed generic(s). In the present instance, the claimed invention contains no identifying characteristics regarding the probes used in the claimed method.

An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004).

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. > Enzo Biochem, 323 F.3d at 964, 63 USPQ2d at 1613.

The instant invention does not disclose the probes or the structure of the probes. The instant disclosure is based on a mere plan, since no working examples are present.

The claimed method depends upon identifying nucleic acid sequence probes after hybridizing with known IBD gene set, and prepare microarrays using the identified probes and use the array in the claimed method. The specification has not disclosed any working examples or experiments in which the genes involved in up- or down- regulated in intestinal tissue of a patient are identified and thus identified genes are used in the claimed method.

The specification in page 3 discloses that the hypothetical probes have sequences which would be either about 80 % identical or about 100 % identical to at least about 12 to about 40 consecutive nucleotides of the genes of Table 1. The specification has not disclosed, i.e., the probes which are designed based on the above disclosure, which are roughly 80 % or 100 % identical to a 12 nucleotide fragment of the disclosed genes would hybridize to the genes in Table 1 and are useful in the claimed method. The specification lacks written description of the claimed invention in view of no working examples, and lack of specific sequence of the probes.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 30-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites the limitation "the mRNA" in step a), line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 30 is vague and indefinite by reciting 'determining an approximate amount of hybridization'. The metes and bounds of the term 'approximate amount' is not known. And further claim 31 recites that the 'amount of hybridization is either more or less by at least a factor

of two' which is indefinite. Applicants are requested to clarify which amount of hybridization is considered as a factor of at least two.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al (Digestive Diseases and Sciences, Vol. 41, No. 4 (April 1996), pp 660-669) and Poulakkainen (G4358), and Prehn et al (G4355) (Gastroeterology, vol 114, No. 4, April 1998) and further in view of specification disclosure.

Alexander et al disclose a method to determine altered expression of protooncogenes (cell cycle related genes) in patients with inflammatory bowel disease (IBD). The reference assayed transcripts of 15 protooncogenes (refer to IBD genes) in colonic epithelial cells of IBD patients and controls (e.g., see abstract). The reference discloses that increased levels (refers to the differential expression of the instant claim) of soluble mediators (e.g. Leukotrienes,

prostaglandins) of inflammation as well of the cells of immune system have been found to be present in the intestinal mucosa and submucosa of IBD patients (e.g., see page 660, last paragraph bridging first paragraph in page 661). The reference discloses expression of transcripts of eight growth factor receptor related genes in colonic epithelial cells of IBD patients and controls (i.e., see left column in page 661). The reference discloses that increased expression of PDGF-R- mRNA involved epithelium, compared to matched uninvolved epithelium, and the transcript level of this gene, as well three other growth factors was considerably higher in colonic epithelial cells of IBD patients (i.e., see page 661).

The reference discloses that prior to determining whether there were any differences between IBD samples and controls in their relative expression of protooncogene transcripts, it was necessary to determine the degree of expression of each of the genes in normal colon epithelial cells (i.e., see page 662, right column, section under results). The reference discloses that hybridization of radio labeled probes to slot blots of RNA extracted from normal epithelial cells of patients rejected for diverticulitis and sporadic cancer revealed that transcripts of five protooncogenes were abundant in these samples (refers to a method of selecting genes involved in IBD). The reference discloses that the level of expression of *c-fos* in the involved IBD samples was about twofold higher than in the uninvolved IBD samples.

The claimed invention differs from the prior art teachings by reciting the use of at least 5 probes which are at least 12 nucleotides in length, and complementary to a gene shown in table 1 (or 10, or 25 or 50 or 75 different nucleic acid probes). Alexander et al teach the expression of protooncogenes in inflammatory bowel disease. Alexander et al teach a method to determine the differential expression of genes involved in IBD. The instant claim recites at least 5 different

probes, and each probe is complementary to a mRNA of a gene shown in Table 1. However, the genes in the instant specification table 1 are not novel genes, and are well known for their role in IBD. The specification in page 19, discloses 'Table 1 indicates those sequences which are over- or underexpressed in a CD- or UC_derived cells relative to normal tissue.' Applicants in the specification disclose the Genbank accession numbers of the genes used in the claimed method. Thus, all the genes used in the claimed method are well known in the art.

Puolakkainen et al (G4358) teach distinct expression profiles of stromelysin-s, collagenase and MMP-12 in intestinal ulcerations. Note that the crohn's disease (CD), ulcerative colitis (UC) are part of larger group of IBDs. And Prehn et al teach the role of TNF-alpha in CD, IL-18, IL-12, IL-10, IL-4. Thus, it would have been obvious to one skilled in the art at the time the invention to use all the known genes involved in IBD and use the genes (or probes) in array format to determine the IBD or pre-IBD phenotype. A person skilled in the art would have been motivated to use all the known genes or genetic markers involved in IBD in an array format to screen IBD cells, such that the efficiency of the method improves (i.e., more markers used the more different mechanisms involved in IBD are determined).

12. Claims 30-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dieckgraefe et al (Gastroeterology, vol 114, No. 4, April 1998) and Poulakkainen (G4358).

Dieckgraefe et al disclose a method for identifying gene expressed in IBD. The reference has used GeneChip expression monitoring system to examine mucosal gene expression in ulcerative colitis, Crohns' colitis, and both in inflamed and non-inflamed non IBD specimens. The reference's aim was to identify gene markers differentially expressed in Crohns' disease and ulcerative colitis; identify genotype associated with disease subsets and characteristics. The

reference in methods disclose RNA isolated from the mucosa of colonic reaction specimens was used to generate hybridization probes, and light directed solid-phase combinatorial chemistry was used to generate oligonucleotide probe array. The reference in results section discloses that dramatic changes were seen in the expression of wide range of genes, and genes were identified which appear to be specific markers for the specific diagnosis, disease activity and specific feature of histology. Dieckgraefe et al conclude that oligonucleotide array hybridization provides a sensitive, reproducible methods for monitoring differential gene expression in disease tissue. The reference clearly do not recite the genes or probes used in the method, however the reference disclosure that the genes involved in the ulcerative colitis and Crohn's disease from specimens of both inflamed and non-inflamed IBD specimens indicate that any IBD marker genes or probes can be used in the method.

The claimed invention differs from the prior art teachings by reciting 'contacting the mRNA of test cell with at least 5 different nucleic acid probes, wherein each probe is at least 12 nucleotides in length and is complementary to mRNA of a gene in Table 1.' Dieckgraefe et al teach a method of identifying gene expression in IBD using Genechip technology. Dieckgraefe et al do not teach the genes in the table 1. However, the genes shown in Table 1 are publicly known and available. And Puolakkainen et al (G4358) teach distinct expression profiles of stromelysin-s, collagenase and MMP-12 in intestinal ulcerations. Note that the crohn's disease (CD), ulcerative colitis (UC) are part of larger group of IBDs. Thus a person skilled in the art would have motivated to use the method of Dieckgraefe et al and the genes known to be involved in CD or UC in determining the differential expressed genes in IBD. Thus, a person skilled in the art at the time the invention was filed would have motivated to use the well known genes in the

method taught by Dieckgraefe et al because Dieckgraefe et al teach the advantages of using Genechip technology in high through-put diagnostic assay.

13. Claims 30-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dieckgraefe et al (Gastroeterology, vol 114, No. 4, April 1998) and in view of specification disclosure.

Dieckgraefe et al disclose a method for identifying gene expressed in IBD. The reference has used GeneChip expression monitoring system to examine mucosal gene expression in ulcerative colitis, Crohns' colitis, and both in inflamed and non-inflamed non IBD specimens. The reference's aim was to identify gene markers differentially expressed in Crohns' disease and ulcerative colitis; identify genotype associated with disease subsets and characteristics. The reference in methods disclose RNA isolated from the mucosa of colonic reaction specimens was used to generate hybridization probes, and light directed solid-phase combinatorial chemistry was used to generate oligonucleotide probe array. The reference in results section discloses that dramatic changes were seen in the expression of wide range of genes, and genes were identified which appear to be specific markers for the specific diagnosis, disease activity and specific feature of histology. Dieckgraefe et al conclude that oligonucleotide array hybridization provides a sensitive, reproducible methods for monitoring differential gene expression in disease tissue. The reference clearly do not recite the genes or probes used in the method, however the reference disclosure that the genes involved in the ulcerative colitis and Crohn's disease from specimens of both inflamed and non-inflamed IBD specimens indicate that any IBD marker genes or probes can be used in the method.

The claimed invention differs from the prior art teachings by reciting 'contacting the mRNA of test cell with at least 5 different nucleic acid probes, wherein each probe is at least 12

nucleotides in length and is complementary to mRNA of a gene in Table 1. Dieckgraefe et al teach a method of identifying gene expression in IBD using Genechip technology. Dieckgraefe et al do not teach the genes in the table 1. The specification discloses that 'Table 1 indicates those sequences which are over- or under expressed in a CD- or UC-derived cells relative to normal tissue' (see specification page 19, lines 6-7), and further provides gene accession numbers of the genes (thus the genes are publicly available). Thus a person skilled in the art would have motivated to use the method of Dieckgraefe et al and the known genes in determining the differential expressed genes in IBD. All the genes used in the claimed method are well known in the art. Thus, a person skilled in the art at the time the invention was filed would have motivated to use the well known genes (all these genes are known to have a role in IBD) in the method taught by Dieckgraefe et al because Dieckgraefe et al teach the advantages of using Genechip technology in high through-put diagnostic assay.

Response to Arguments

14. Applicant's arguments with respect to claims 30-41 have been considered but are moot in view of the new ground(s) of rejection.

15. Applicant's arguments filed on 3/29/05, regarding written description rejection has been fully considered but they are not persuasive. Applicants assert that the specification as filed contains adequate written description of the new claims 30-41. Applicants argue that the specification discloses nucleic acid probes of at least 12 nucleotides in length having a sequence complementary to nucleic acid sequences set forth in Table 1. Applicants arguments have been

considered and are not persuasive, because the instant claim probes are at least 12 nucleotides in length and complementary to mRNA of gene shown in table 1. And further applicants argue that 'the probes generally hybridize under stringent conditions to the nucleic acid sequence and are at least 80 % identical to the nucleic acid sequences.' However, the specification has not disclosed the probes which are at least 12 nucleotides in length, and hybridize under stringent condition to the genes of Table 1, and are at least 80% identical to the nucleic acid sequence of the genes in Table 1. The specification has only disclosed the desirable functions of the virtual probes. However, the specification has not disclosed the probes, which are at least 12 nucleotides in length, and hybridize under stringent condition to the genes of Table 1, and at least 80% identical to the nucleic acid sequence of the genes in Table 1. The specification further explains the use of the virtual probes in assay methods. No examples of assay methods in which the probes have been used are disclosed. Thus, the invention lacks written description.

16. Applicant's arguments filed on 3/29/25, regarding the rejection of claims over Alexander et al, Puolakkainen et al, and Prehn et al have been fully considered but they are not persuasive. Applicants argue that the newly added claims recite 'contacting mRNA of a test cell with at least different nucleic acid probes, wherein each probe is at least 12 nucleotides in length and is complementary to the mRNA of a gene in Table 1. Applicants arguments have been considered and are not persuasive, since the rejection is based on combined teachings of Alexander et al, Puolakkainen et al, and Prehn et al, and all the references teach IBD and genes involved in IBD and methods of identifying differential expression of the IBD genes. The references may be silent regarding the several different genes shown in Table 1 of the instant specification. However, the instant claims do not recite that the 5 different nucleic acid probes are

complementary to 5 different genes shown in Table 1 as in applicant's arguments. The instant claims recite 'at least 5 different nucleic acid probes, wherein each probe is at least 12 nucleotides in length and is complementary to the mRNA of **a gene shown in Table 1**. Thus, for the reasons of record the rejection is still applicable to the instant new claims.

17. Applicant's arguments filed on 3/29/05, regarding the rejection of claims over Dieckgraefe et al have been fully considered but they are not persuasive. Applicants argue that although the reference discloses the differential expression of different classes of genes including cell adhesion molecules and reparative factors in IBD specimens, this reference simply fails to reach or suggest determining the presence of differential expression of any of the specific genes shown in table 1. Applicants arguments have been considered and are not persuasive, because the genes disclosed in Table 1 are well known, and further the Dieckgraefe et al disclose the method of in determining the differential expressed genes in IBD. A person skilled in the art would have been motivated to use the known genes in array format to identify the IBD or pre-IBD in test cells because Dieckgraefe et al teaches the advantages of the method.

Conclusion

18. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

07 June 2005

PADMASHRI PONNALURI
PRIMARY EXAMINER